



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

First Named

Inventor : Christopher Lee Berg et al.

Appln. No.: 10/623,179

Filed : July 18, 2003

For : METHOD AND APPARATUS FOR
REPLACING KNEE-JOINT

Docket No.: M81.12-0060

Appeal No.

Group Art Unit: 3732

Examiner: A. Ramana

**TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION - 37 C.F.R. §41.37)**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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7th DAY OF August,
2006
Peter J. Cima
PATENT ATTORNEY

Sir:

Transmitted herewith is the Appeal Brief in this application with respect to the Notice
of Appeal filed on 6-1-06.

FEE STATUS

[x] Small entity status under 37 C.F.R. §§ 1.9 and 1.27 is established by a verified
statement.

FEE FOR FILING APPEAL BRIEF

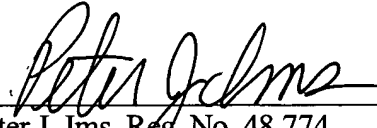
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The Director is authorized to charge any additional fees associated with this paper or credit any overpayment to Deposit Account No. 23-1123. A duplicate copy of this communication is enclosed.

Respectfully submitted,

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BRIEF FOR APPELLANT

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22313-1450, THIS

1st DAY OF August, 2006.
Peter J. Ma
PATENT ATTORNEY

Sir:

This is an appeal from an Office Action mailed on 1, 2006 in which claims 9-19
were finally rejected, claims 20-22 were objected to and claims 1-8 were allowed.

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REAL PARTY IN INTEREST

Minnesota Scientific, Inc., a corporation organized under the laws of the state of Minnesota, and having offices at 4859 White Bear Parkway, St. Paul, MN 55110-3325, has acquired the entire right, title and interest in and to the invention, the application, and any and all patents to be obtained therefor, as set forth in the Assignment filed with the patent application and recorded on November 17, 2003 at Reel 014715, frame 0536.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

STATUS OF THE CLAIMS

I.	Total number of claims in the application.	
	Claims in the application are:	1-22
II.	Status of all the claims.	
A.	Claims cancelled:	None
B.	Claims withdrawn but not cancelled:	None
C.	Claims pending:	1-22
D.	Claims allowed:	1-8
E.	Claims rejected:	9-19
F.	Claims Objected to:	20-22
III.	Claims on appeal	
	The claims on appeal are:	9-19

STATUS OF AMENDMENTS

An amendment was filed on April 28, 2006 subsequent to the final rejection to respond to an objection to the claim language in claim 22. The amendment to claim 22 was entered into the record in an Advisory Action mailed on May 16, 2006.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention as defined in independent claim 9 includes an apparatus for use in performing a knee-joint replacement surgery on a surgical table where the surgery involves the tibia and femur joined at the knee joint. (page 4, lines 10-12). The apparatus includes a retractor support rigidly mounted to the surgical table. (page 3, line 25 – page 4, line 9). The apparatus also includes a plurality of retractors that are attached to the retractor support where each of the plurality of retractors includes a blade for engaging skin and flesh layers proximate the knee-joint. (page 14, lines 17-23). At least one of the retractors has a flexible portion that flexes (page 5, lines 15-24) sufficiently so that the tibia may be moved during the surgery without having to re-engage the retractors with flesh and skin layers or to reattach the retractors to the retractor support or adjust the retractor support. (page 4, line 28 – page 5, line 2).

Claim 17 defines a method of holding down the lower leg portion during knee surgery where the method includes position in the knee such that the knee is in an elevated and bent position facing generally upwardly. (page 4, lines 10-12). The method also includes positioning a retractor support mounted to a surgical table where the retractor support has first and second arms that extend along opposite sides of the knee. (page 3, line 25 – page 4, line 9). The method also includes positioning a flexible strap between distal ends of the first and second arms such that the flexible strap engages the lower leg with a downward force to retain the lower leg in a selected position during surgery. (page 7, line 26 –page 8, line 8).

Claim 19 defines an apparatus for use in securing a lower leg portion in a knee surgery on a surgical table where the knee is in an elevated and bent position. (page 4, lines 10-12). The apparatus includes a retractor support mounted to a surgical table where the retractor support has first and second arms that are extendible along opposite sides of the knee and have distal end portions. (page 3, line 25 – page 4, line 9). The apparatus also includes a flexible strap extending between the distal end portions of the first and second arms for engaging the lower leg such that a generally downward force is applied against the lower leg to retain the lower leg in position. (page 7, line 26 –page 8, line 8).

ISSUES

- I. Whether claims 9-16 of the present application are unpatentable as being obvious over the combination of U.S. Patent No. 6,190,312 (hereinafter “the ‘312 patent”) in view of U.S. Patent No. 5,964,698 hereinafter (hereinafter “the ‘698 patent”) and U.S. Patent No. 4,813,401 (hereinafter “the ‘401 patent”).
- II. Whether claim 19 of the present application is anticipated by U.S. Patent No. 4,373,709 (hereinafter “the ‘709 patent”).
- III. Whether claims 17 and 18 of the present application are unpatentable as being obvious by the ‘709 patent.

ARGUMENT

I. Claims 9-16 Are Novel Over the Combination of the '312 Patent in view of the '698 Patent and the '401 Patent.

The Examiner erroneously rejected claims 9-16 as being obvious under 35 U.S.C. § 103(a) over the combination of the '312 patent in view of the '698 patent and the '401 patent. The Examiner improperly combined the '312 patent with the '698 patent and the '401 patent to allege that claims 9-16 are obvious as there is no teaching in either patent to suggest the combination. The only reason for combining the two references is hindsight reconstruction which is improper.

A. Standard for a Proper Obviousness Rejection

The Examiner erroneously rejected claims 9-16 as being obvious under 35 U.S.C. § 103(a) over the combination of the '312 Patent in view of the '698 Patent and the '401 Patent. 35 U.S.C. § 103(a) is as follows:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a).

Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966),

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the

obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

B. Claims 9-16 are Novel and Non-Obvious Over the Combination of the '312 Patent in view of the '698 Patent and the '401 Patent.

The Office Action improperly rejected claims 9-16 as being anticipated by Fowler Jr. U.S. Patent No. 6,190,312 (hereinafter the '312 patent) in view of Fowler U.S. Patent No. 5,964,698 (hereinafter the '698 patent) and Greishaber U.S. Patent No. 4,813,401 (hereinafter the '401 patent). However, there is no teaching or suggestion, absent the claimed invention, to combine the '312 patent with the '698 patent and the '401 patent.

The Office Action alleged that the '312 patent discloses a conventional and variable geometry retractor frame with arms 12a and 12b and a retractor stay apparatus attached to an elastic member is received in a notch of a member attached to the frame. The Office Action also alleged that the '312 patent discloses all the elements of the claimed invention except for the frame being attached to the rail of the surgical table and a retractor stay apparatus such as a blade.

The Office Action further alleged that retractor stay member such as paddles or "blades" and hooks attached to elastic members are well known and are shown at Figure 6 and col. 1, lines 44-52. The Office Action also alleged that the '401 patent teaches supporting a retractor frame by mounting it to a rail of a surgical table at Fig.1 and columns 5 and 6.

The Office Action concluded that it would have been obvious to one of ordinary skill in the art at the time that the invention was made to have provided the stay members such as blades in the '312 patent since stay members are well known in the art for retracting tissue. The Office Action also concluded that it would have been obvious to one of ordinary skill in the art at the time that the invention was made to mount the retractor apparatus of the combined '312 patent and the '698 patent to an operating table, as taught by the '401 patent, as it is common

knowledge in the retracting art to support a conventional retractor frame by mounting it a surgical table.

Applicants respectfully disagree that claim 9 is made obvious by the '312 patent in view of the '698 patent and the '401 patent because there is no teaching or suggestion to combine the '312 patent with the '401 patent. In *In re Dembiczak*, 175 F.3d 994, 50 U.S.P.Q. 2d 1614 (Fed. Cir. 1999), the Federal Circuit emphasized that, to reject an inventor's claim for obviousness in view of a combination of prior art references, a showing of a suggestion, teaching or motivation must be "clear and particular". The mere fact that prior art can be modified does **not** make the modification obvious unless the prior art taught or suggested the desirability of the modification. *In re Gordon*, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). (emphasis added)

Claim 9 defines an apparatus for use in performing a knee-joint replacement surgery on a surgical table where the surgery involves the tibia and femur joined at the knee joint. The apparatus includes a retractor support rigidly mounted to the surgical table. The apparatus also includes a plurality of retractors that are attached to the retractor support where each of the plurality of retractors includes a blade for engaging skin and flesh layers proximate the knee-joint. At least one of the retractors has a flexible portion that flexes sufficiently so that the tibia may be moved during the surgery without having to re-engage the retractors with flesh and skin layers or to reattach the retractors to the retractor support or adjust the retractor support.

In contrast to the claimed invention, the '312 patent discloses a variable geometry retractor frame that is conformed to fit a surface of the patient's body at a surgical site. (Col. 4, lines 59-63 and Col. 8, lines 13-14). The variable geometry frame allows for improved placement of the clips on the frame where the clips engage an elastic member that is utilized to retract flesh. (Col. 3, lines 37-41).

The retractor frame is supported by a patient's body to provide adequate support for the elastic member that is utilized to retract flesh. However, it is not understood how the device disclosed in the '312 patent could be utilized to perform a knee-joint surgery where the tibia is moved because as the tibia is moved, the support for the retractor frame would also move and require adjustment of the retractors.

The '401 patent discloses a table mounted retractor support that supports retractors having hinged, rigid handles that do not hinder the surgeon's movement during the operation. (Col. 2, lines 31-35). The '401 patent also discloses a retractor holder that is easily movable to a new position on the retractor frame without having to disturb the position of the other retractor structures. (Col. 2, lines 42-45).

There is no clear and particular motivation, teaching or suggestion that would lead one of ordinary skill in the art to combine a reference that discloses a variable geometry retractor frame that is supported by the patient's body to provide better placement of retractors with a reference that discloses retractors with rigid, hinged handles and an improved clamp for a table mounted support to provide better access to a surgical site to allege that the claimed invention is obvious. *In re Clay*, 966 F.2d 656, 659-60 (Fed. Cir. 1992) (A reference that discloses the same purpose as the claimed invention relates to the same problem and that fact supports use of the reference in an obviousness rejection.) Neither reference addresses the purpose of the claimed invention where the tibia is moveable during a knee-joint replacement surgery without re-engaging the retractors with the flesh or reattaching the retractors to the support.

As is clear from the above discussion, the Office Action used the claimed invention as a road map to allege that claim 9 is obvious, as there is no teaching, suggestion or motivation to make the combination of references. Therefore, the obviousness rejection of claim 9 is improper and should be reversed.

The Office Action also rejected dependent claims 10-16 as being obvious over the '312 patent in view of the '401 patent and the '698 patent. Since claim 9 is in allowable form, claims 10-16, which depend from independent claim 9, are also in allowable form. Reversal of the obviousness rejection of claims 10-16 are respectfully requested.

II. Claim 19 is Novel and not Anticipated by the '709 Patent.

The Office Action erroneously rejected claim 19 as under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,373, 709 (hereinafter the '709 patent). In the March 1, 2006 Office Action, the Office Action alleged that the '709 patent discloses a surgical limb holder 10 that can be used to hold a limb in any position, the holder mounted to a surgical table having a support 11, arms 29 and a flexible strap 42 that can be used to restrain a lower portion of a leg or "lower leg" (Figs. 1

and 3, col. 1, lines 19-21 and col. 2, lines 18-39).

Applicants respectfully disagree that the '709 patent anticipates claim 19. Claim 19 defines the retractor support as being mounted to the surgical table and having first and second arms that are extendable along opposite sides of the knee. There is no disclosure in the '709 patent of the defined structure.

Rather, the '709 patent discloses an upwardly extending generally U-shaped support that engages the circumference of the thigh. The support disclosed in the '709 patent is not extendable along opposite sides of the knee as claimed.

Claim 19 also defines the present invention as having a flexible strap extending between the distal end portions of the support arms for engaging the lower leg to provide a generally downward force against the lower leg to retain the lower leg in position. In contrast, the strap disclosed in the '709 patent is not utilized to provide a downward force to the thigh. Rather the '709 patent discloses that the strap may be utilized to further restrain a limb. See Col. 3, lines 23-25. The strap in the '709 patent does not provide a downward force to retain the lower leg in position as claimed.

The Examiner relies upon *In re Schreiber* to maintain the anticipation rejection of claim 19 by stating that claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). However, the anticipation rejection in *In re Schrieber* was affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner). 44 USPQ2d 1429, 1432-33.

As an analogy, one would not conclude that a pencil anticipates a pool cue or vice versa because neither could perform the function of the other. However, each has a shaft that tapers to a point on one end (for writing and striking a pool ball) and a rubber component attached to the opposite end (an eraser and a cushion).

Just as a pool cue does not anticipate a pencil and vice versa, a U-shaped support 13 attached to a substantially vertical stanchion member 11, irrespective of the rotational movement about its axis and height, as disclosed in the '709 patent would be positioned substantially vertically

around opposite sides of the knee. To then attach the strap 40 to the ends of the support members 13 would obstruct access to the knee joint and prevent or hinder the surgical procedure. Therefore, the device disclosed in the '709 patent is not capable of being positioned on opposite sides of the knee and also retain the lower leg as claimed for a knee joint surgery.

Also, the Examiner relies upon the statement that the device disclosed in the '709 patent is adjustable such that the limb can be held in any position which will enhance or facilitate surgery (Col. 1, lines 19-22). However, the '709 patent discloses that the stanchion member 11 slides and rotates within the vice 14 to adjust the height and attitude of the support. (Col. 2, lines 18-21 and lines 27-31). The position of the device relative to the patient is adjusted by moving the vice 14 along the sides or ends of the operating table on a track 38. (Col. 2, lines 23-26). Movement along the track 38 of an operating table and vertical and rotational movement of the stanchion within the vice, does not provide movement to of the device into any position that will enhance surgery as the device is only useful when the limb to be operated upon is near the edge of the operating table.

Further, the Office Action ignores the stated purpose of the device disclosed in the '709 patent. The structure of the '709 patent has the "important advantage" of "arranging and holding the limb 35 over the edge (i.e. dangling over) of the operating table 37. This permits the joint to be flexed and fully bent as necessary during the operating procedures" (column 3, lines 17-22).

Contrary to the allegations in the Office Action, the structure disclosed in the '709 patent is not capable of being positioned along opposite sides of the knee and having a flexible strap therebetween for engaging the lower leg as claimed while being able to perform a knee surgery. Therefore, the '709 patent does not anticipate claim 19 and Applicants respectfully request that the rejection be reversed.

III. Claims 17 and 18 are Novel and Non-Obvious Over the '709 Patent.

Claim 17 was erroneously rejected under 35 U.S.C. § 103(a) as being obvious over the '709 patent. The Office Action alleged that because the '709 patent discloses that the limb holder 10 can be utilized in any position that will enhance and facilitate surgery (Col. 1, lines 6-22) and therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the limb holder 10 to restrain the lower leg or "tibia" to provide support without discomfort.

Applicant incorporate the arguments with respect to claim 19 into the arguments made with respect to claim 17. Further, Applicants respectfully disagree that claim 17 is made obvious by the '709 patent. It would make no sense to use the structure disclosed in the '709 patent to support the lower leg. The joint (knee) could not be flexed and fully bent as necessary during the operating procedure discussed in the '709 patent. (column 3, lines 17-22). The structure of '709 has the "important advantage" of "arranging and holding the limb 35 over the edge (i.e. dangling over) of the operating table 37. This permits the joint to be flexed and fully bent as necessary during the operating procedures" *Id.*

If the lower leg was secured in the structure of the '709 patent, it could not be bent because the support structure provides an upward force to the leg. An upward force is the opposite of the downward force as claimed in claim 17.

Further, there is no disclosure in the '709 patent of positioning first and second arms of a retractor support along opposite sides of the knee. It would not make sense to position the U-shaped support as disclosed in the '709 patent underneath the knee joint with the side arms extending upward around the knee joint as access to the knee joint would be obscured by the support. Additionally, it is unclear how the apparatus could be positioned about the knee while maintaining the knee in an elevated and bent position as claimed.

Finally, although the phrase "the lower leg" is not specifically defined in the present application, it is understood that this is the portion of the anatomy that is below the knee joint. See Exhibits A, B and C which were attached to an Amendment dated September 21, 2005 and received by the United States Patent and Trademark Office as evidenced by the postcard date stamped September 23, 2005, a copy of which is also attached as Exhibit D. Exhibits A, B and

C are copies of websites that describe the anatomy of the leg. The area above the knee is generally referred to as the thigh area that is supported by the tibia. The area below the knee has been referred to as "the lower leg", therefore the phrase "lower leg" in the claims refers to that portion of the leg below the knee. Therefore, there is no disclosure of the device disclosed in the '709 patent being utilized to provide a downward force on the lower leg.

For the forgoing reasons claim 17 is not made obvious by the '709 patent. Applicants respectfully request that the rejection be reversed.

Claims 18 depends from independent claim 17. Since claim 17 is in allowable form, claims 18 is also in allowable form. Applicants respectfully request that the rejection of claim 18 be reversed.

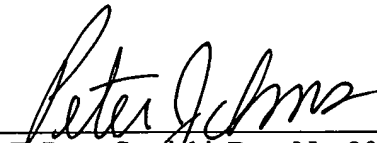
CONCLUSION

Applicants respectfully submit that claims 9-19 are allowable over the prior art. Applicants therefore request reversal of the rejections of claims 9-19.

Respectfully submitted,

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Appendix A

CLAIMS INVOLVED IN APPEAL:

1.(Previously Presented) A method of performing a knee-joint replacement surgery involving a tibia and femur, the method comprising:

positioning the tibia and the femur such that a knee joint is disposed in a bent position;

incising skin and flesh layers to expose the knee-joint;

positioning a retractor support extending along at least opposite sides of the knee joint;

retracting the skin and flesh layers proximate the knee-joint utilizing a plurality of retractors attached to the retractor support with at least one of the retractors being attached to the retractor support such that the retractor may be flexed sufficiently to be able to move the knee-joint during the surgery without repositioning the retractors.

2.(Original) The method of claim 1 wherein the retractor support is mounted to the surgical table.

3.(Original) The method of claim 2 wherein the retractor support is mounted to a rail of the surgical table.

4.(Original) The method of claim 1 wherein the at least one of the retractors is attached to the retractor support with a flexible cord.

5.(Original) The method of claim 4 wherein the flexible cord is attached to the retractor support by engaging a member that is rigidly attached to the retractor support, the member having a V-shaped groove wherein the cord engages the groove.

6.(Original) The method of claim 1 wherein the retractor support includes two support arms, each arm extending along an opposite side of the knee-joint.

7.(Original) The method of claim 6 and further including positioning the support arms below the knee-joint.

8.(Original) The method of claim 1 wherein each of the plurality of retractors are attached to the retractor support in a manner that each of the retractors may be flexed so that the knee joint may be moved during surgery without repositioning the retractors.

9.(Previously Presented) An apparatus for use in performing a knee-joint replacement surgery on a surgical table, the surgery involving a tibia and femur joined at a knee joint, the apparatus comprising:

a retractor support rigidly mounted to the surgical table; and

a plurality of retractors attached to the retractor support and each having a retractor blade for engaging skin and flesh layers proximate the knee-joint wherein at least one of the retractors has a flexible portion that flexes sufficiently so that the tibia may be moved during the surgery without having to re-engage the retractors with the flesh and skin layers or to reattach the retractors to the retractor support or adjust the retractor support.

10.(Original) The apparatus of claim 9 wherein the surgical table includes a rail and wherein the retractor support is rigidly mounted to the rail of the surgical table.

11.(Original) The apparatus of claim 9 wherein the at least the one of the retractors includes a flexible cord attached to the retractor blade, the cord having a free end that is securable to the retractor support.

12.(Original) The apparatus of claim 11 and further including an attaching device fixedly attached to the retractor support and having a V-shaped groove engaging the free end of the cord.

13.(Previously Presented) The apparatus of claim 9 wherein the retractor support includes at least two arms, each arm being positionable along opposite sides of the knee joint.

14.(Previously Presented) The apparatus of claim 13 wherein the arms of the retractor support are positionable below the knee joint.

15.(Original) The apparatus of claim 9 wherein each of the plurality of retractors has a flexible portion which flexes sufficiently to move the tibia during surgery without having to re-engage the retractors with the flesh and skin layers or reattaching the retractors to the retractor support or adjust the retractor support.

16.(Original) The apparatus of claim 15 wherein each of the retractors includes a flexible cord having a free end that is attachable to the retractor support.

17.(Previously Presented) A method of holding down a lower leg portion during knee surgery, the method comprising:

positioning the knee such that the knee is in an elevated and bent position facing generally upwardly;

positioning a retractor support mounted to a surgical table, the retractor support having first and second arms that extend along opposite sides of the knee; and

positioning a flexible strap extending between distal ends of the first and second arms such that the flexible strap engages the lower leg with a downward force to retain the lower leg in a selected position during surgery.

18.(Original) The method of claim 17 wherein the retractor support is mounted to a rail of the surgical table.

19.(Previously Presented) An apparatus for use in securing a lower leg in knee surgery on a surgical table wherein a knee is disposed in an elevated position, the apparatus comprising:

a retractor support mounted to the surgical table wherein the retractor support

includes first and second support arms that are extendable along opposite sides of the knee, each support arm having distal end portions; and

a flexible strap extending between the distal end portions of the support arms for engaging the lower leg such that a generally downward force is applied against the lower leg to retain the lower leg in position.

20.(Original) The apparatus of claim 19 and further including first and second downwardly extending rigid leg portions extending from the first and second distal end portions of the first and second support arms and wherein the strap is fixedly attached to the first and second leg portions.

21.(Original) The apparatus of claim 20 wherein the strap is attached to the first and second leg portions below where the strap engages the lower leg.

22. (Currently Amended) The method of claim 17 wherein the flexible strap is attached to the arms at a position below the point at which the strap engages the lower leg for applying a force to the lower leg.

Appendix B

EVIDENCE INDEX

Applicant has submitted no evidence under 37 C.F.R. §§ 1.130, 1.131 or 1.132.

Applicant submitted three webpages on September 21, 2005 that it is relying upon. The Examiner cited four references in the final office action.

Applicants cited the webpages that were attached to a September 21, 2005 amendment and are attached hereto as Exhibits A-C.

Applicants cited the return postcard date stamped September 23, 2005 proving that Exhibits A-C were received by the United States Patent and Trademark Office which is attached as Exhibit D.

The Examiner cited U.S. Patent No. 6,190,312 in an Office Action, a copy of which is attached hereto as Exhibit E.

The Examiner cited U.S. Patent No. 5,964,698 in an Office Action, a copy of which is attached hereto as Exhibit F.

The Examiner cited U.S. Patent No. 4,813,401 in an Office Action, a copy of which is attached hereto as Exhibit G.

The Examiner cited U.S. Patent No. 4,373,709 in an Office Action, a copy of which is attached hereto as Exhibit H.

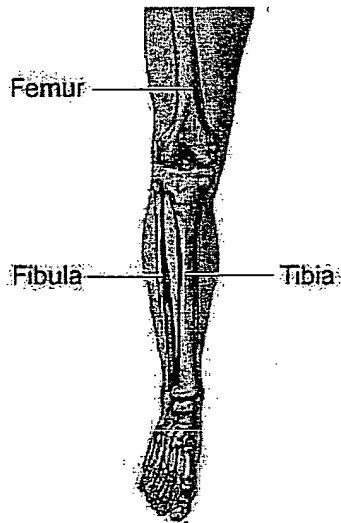
[General Notes]

Only 1 copy of the brief is required.

Fee must be submitted with brief.

Send separate transmittal letter.

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The lower leg is comprised of two bones, the tibia and the smaller fibula. The thigh bone, or femur, is the large upper leg bone that connects the lower leg bones (knee joint) to the pelvic bone (hip joint).

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Lower Leg Anatomy

From Elizabeth Quinn, Your Guide to Sports Medicine.

Overview

While there are many muscles located in the lower leg, three are most well known. The muscles that make up the calf - the gastrocnemius and soleus are the power muscles of the lower leg. The anterior tibialis is another well-known muscle of the lower leg that often gets the blame for shin splints. Lastly, the famous achilles tendon is located in the lower leg, and is the culprit of many lower leg pain and injury. This introduction to the anatomy of the foot and ankle will not be exhaustive, but rather try and highlight the structures that will be discussed in the sections below.

Bones and Joints

The Lower Leg is comprised of two long bones. The tibia is the larger of the two, and is located toward the middle of the lower leg (medially). The fibula is the smaller bone and it is located on the outside of the lower leg (laterally). The bump on the outside of the lower leg (that we call our ankle) is actually the distal end of the fibula. Muscles

The lower leg is divided into four compartments that contain the various muscles of the lower leg.

The anterior compartment

(the front of the shin) holds the tibialis anterior, the extensor digitorum longus, the extensor hallucis longus and the peroneus tertius muscles. These muscles dorsiflex the foot and toes (pull the foot and toes upward). The tibialis anterior also assists turning the foot inward. To feel these muscles contract, place your hand just to the outside of the tibia and pull the foot up.

The lateral compartment

is along the outside of the lower leg. It contains the peroneus longus and peroneus brevis muscles. These muscles pull the foot outward. They also aid in plantarflexion (pointing the foot). To feel these muscles contract, place your hand on the outside of your shin and turn your foot out.

The posterior compartment

holds the large muscles that are most commonly known as the calf muscles: the gastrocnemius and soleus. It also contains plantaris muscle. The gastrocnemius is shorter, and thicker and has two heads (or attachments), an inner and an outer. It is the most visible of the calf muscles. The soleus lies just underneath, and while the plantaris is located in the back wall of the knee joint. All three of these muscles converge into the thick achilles tendon that inserts at the base of the heel. The main function of these is plantarflexion, which is what helps to propel you forward in running, or up as in stair climbing. The gastrocnemius and plantaris also have the distinction of being two-joint muscles, crossing both the knee and the ankle.

The deep posterior compartment

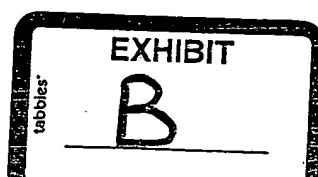
is deep within the back of the lower leg. Beginning in the back of the tibia these muscles converge near the ankle as three distinct tendons. They are the tibialis posterior, flexor digitorum longus, and flexor hallucis longus. All three aid in plantarflexion, but each has its own primary function. Tibialis posterior pulls the foot inward, flexor digitorum longus flexes the toes, and flexor hallucis longus flexes the big toe.

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About

Knee Anatomy and Physiology

From Elizabeth Quinn, Your Guide to Sports Medicine.

What Causes Knee Pain?

Some knee problems result from wear of parts of the knee, such as occurs in osteoarthritis. Other problems result from injury, such as a blow to the knee or sudden movements that strain the knee beyond its normal range of movement.

How Can People Prevent Knee Problems?

- First warm up by walking or riding a stationary bicycle, then do stretches before exercising or participating in sports. Stretching the muscles in the front of the thigh (quadriceps) and back of the thigh (hamstrings) reduces tension on the tendons and relieves pressure on the knee during activity.
- Strengthen the leg muscles by doing specific exercises (for example, by walking up stairs or hills, or by riding a stationary bicycle). A supervised workout with weights is another pathway to strengthening leg muscles that benefit the knee.
- Avoid sudden changes in the intensity of exercise. Increase the force or duration of activity gradually.
- Wear shoes that both fit properly and are in good condition to help maintain balance and leg alignment when walking or running. Knee problems may be caused by flat feet or overpronated feet (feet that roll inward). People can often reduce some these problems by wearing special shoe inserts (orthotics). Maintain appropriate weight to reduce stress on the knee.

Knee Anatomy

The knee joint works like a hinge to bend and straighten the lower leg. It permits a person to sit, stand, and pivot. The knee is composed of the following parts:

Bones and Cartilage

The knee joint is the junction of three bones—the femur, the tibia and the patella. The ends of the bones are covered with articular cartilage, a tough, elastic material that helps absorb shock and allows the knee joint to move smoothly. Separating the bones of the knee are pads of connective tissue called menisci, which are divided into two crescent-shaped discs positioned between the tibia and femur on the outer and inner sides of each knee. The two menisci in each knee act as shock absorbers, cushioning the lower part of the leg from the weight of the rest of the body, as well as enhancing stability.

Muscles

There are two groups of muscles at the knee. The quadriceps muscle comprises four muscles on the front of the thigh that work to straighten the leg from a bent position. The hamstring muscles, which bend the leg at the knee, run along the back of the thigh from the hip to just below the knee.

Ligaments

Ligaments are strong, elastic bands of tissue that connect bone to bone. They provide strength and stability to the joint. Four ligaments connect the femur and tibia:

- The medial collateral ligament (MCL) provides stability to the inner (medial) aspect of the knee.
- The lateral collateral ligament (LCL) provides stability to the outer (lateral) aspect of the knee.
- The anterior cruciate ligament (ACL), in the center of the knee, limits rotation and the forward movement of the tibia.
- The posterior cruciate ligament (PCL), also in the center of the knee, limits backward movement of the tibia.

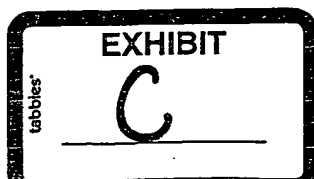
Other ligaments are part of the knee capsule, which is a protective, fiber-like structure that wraps around the knee joint. Inside the capsule, the joint is lined with a thin, soft tissue, called synovium.

Tendons

Tendons are tough cords of tissue that connect muscle to bone. In the knee, the quadriceps tendon connects the quadriceps muscle to the patella and provides power to extend the leg. The patellar tendon connects the patella to the tibia. Technically, it is a ligament, but it is commonly called a tendon.

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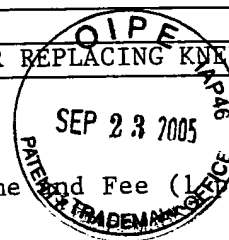


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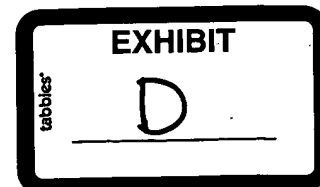
Applicant : Christopher L. Berg et al.
Serial No./Patent No.: 10/623,179
Filed/Issued : July 18, 2003
Title/Mark : METHOD AND APPARATUS FOR REPLACING KNEE JOINT

1. Credit Card Payment Form (1 page)
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4. Amendment (8 pages)
5. Replacement Drawing (1 page; Fig. 2)
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7. Information Disclosure Statement including Form PTO-1449
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